II. REMARKS

Applicant gratefully acknowledges the Examiner's determination that claims 40 and 41 contain allowable subject matter (Office Action, dated March 24, 2008, at 23, lines 1-4).

By the present amendment, claims 40 and 41 have been cancelled, claims 21, 31, 36-39 and 42-45 have been amended, and new claims 48 and 49 have been added. Specifically, independent claims 38 and 39 have been amended to incorporate subject matter of dependent claims 40 and 41, respectively. Therefore, claims 38 and 39 now have the same scope as previous claims 40 and 41.

Claims 21 and 31 have been amended to recite "so that the dissolved substance flows from the means for dispensing into the wearer's mouth" as supported on page 5, lines 1-6, of Applicant's specification as originally filed.

Claims 36 and 37 have been amended to recite "wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member" as supported on page 9, lines 16-24, and by Figure 4, of Applicant's disclosure as originally filed.

Claims 42 and 43 have been amended to recite "wherein the substance has a solid form and the solid form is a solid crystallized form," which is supported by previous claims 42 and 43. Claims 42 and 43 have also been amended to depend on claim 44 and 45, respectively.

Independent claims 44 and 45 have been amended to recite "wherein the substance has a form selected from the group consisting of a solid form and a tablet form" as supported on page 6, lines 10-13, of Applicant's specification as originally filed, and to recite that the substance "is dispensed by dissolving the substance from the stud into the wearer's mouth over time in the wearer's saliva" as supported by previous claim 21.

New claims 48 and 49 depend upon claims 38 and 39, respectively, and additionally recite "wherein the substance comprises a liquid" as supported on page 9, lines 14-16, of Applicant's specification as originally filed.

The present amendment adds no new matter to the above-captioned application.

A. The Invention

The present invention pertains broadly to a method for dispensing a substance into a mouth, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances. In one embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 21. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 31. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 37. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 38. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 39. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 44. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 45.

Various other embodiments, in accordance with the present invention, are recited in the dependent claims. All of the embodiments, in accordance with the present invention, provide the advantage of using a "mouth and tongue stud" to dispense a substance into a wearer's mouth. As would be understood by a person of ordinary skill in the art, a "mouth and tongue stud" is a particular

kind of jewelry having features allowing it to be disposed in the mouth of a wearer.

B. The Rejection

Claims 44 and 45 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

Claims 21-27, 36, 38, 44 and 46 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Kapling, Jr. (U.S. Patent 6,026,659, hereafter the "Kapling Patent") in view of Abramowitz (U.S. Patent 3,500,829, hereafter the "Abramowitz Patent") and Lefkowitz (U.S. Patent 4,676,752, hereafter the "Lefkowitz Patent"). Claims 31, 37, 39, 45 and 47 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the Kapling Patent in view of the Abramowitz Patent and the Lefkowitz Patent. Claims 21-37, 36, 38, 42, 44 and 46 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the Kapling Patent in view of Edwards (U.S. Patent 4,943,274, hereafter the "Edwards Patent") and the Lefkowitz Patent. Claims 31, 37, 39, 43, 45 and 47 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the Kapling Patent in view of the Edwards Patent.

I respectfully traverse the rejections and request reconsideration of the application for the following reasons.

C. Applicant's Arguments

Claims 38 and 39 incorporate allowable subject matter from previous claims 40 and 41, respectively. Therefore, independent claims 38 and 39 are in condition for allowance for the reasons of record.

In view of the present amendment, claims 21-27, 31, 36-39 and 42-49 are in compliance with 35 U.S.C. § 112.

i. The Section 103 Rejection

A prima facie case of obviousness requires a showing that the scope and content of the prior

art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation, or other reason, to combine the references to produce the claimed invention. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). A proper rejection under Section 103 also requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants' disclosure. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). An obviousness analysis, however, is a not a rigid formulaic analysis, but is a flexible determination grounded in the facts of the case. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1739 (2007). Indeed, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007).

In the present case, the Examiner has failed to establish a prima facie case of obviousness against the presently claimed invention because the combination of the Kapling Patent, the Abramowitz Patent, the Lefkowitz Patent, and the Edwards Patent, (i) fails to teach each and every limitation of the claims, (ii) the Examiner has failed to establish any legitimate reason to justify the combination, and (iii) the Examiner has failed to establish that the combination would be enabling and/or that by making the combination a person of ordinary skill in the art would have a reasonable expectation of arriving at the claimed invention.

ii. The Kapling Patent

U.S. Patent 6,026,659, the Kapling Patent, discloses "body jewelry device and method of making the same," wherein, as shown in Figure 1, the body jewelry device (10) includes a post (12) with cap (14) coupled to one end of the post (12) and cap (16) coupled to the other end of the post

(12), (See Kapling Patent, col. 3, lines 38-42). The Kapling Patent, at col. 3, lines 43-44, discloses that the post (12) is disposed in the pieced passageway in a wearer's tongue.

As admitted by the Examiner (Office Action, dated march 24, 2008, at 18-24), the Kapling Patent does not teach, or suggest, "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" as recited by independent claims 21, 31, 36-39, 44 and 45. As also admitted by the Examiner (Office Action, dated march 24, 2008, at 18-24), the Kapling Patent does not teach, or suggest, "dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, 37, 44 and 45.

iii. The Abramowitz Patent

The Abramowitz Patent discloses an "earhole piercing and treating apparatus" as shown in Figures 1 to 13. In an embodiment shown in Figures 4 and 10, the Abramowitz Patent discloses a device comprising a slotted tube (14) provided with an end ball (16) on one end and a squeeze bulb (44) on the other end, (col. 3, lines 17-25). In accordance with this embodiment, the Abramowitz Patent discloses that a medicament or perfume may be placed in the bulb (44) so that when the bulb is squeezed, the medicament is forced out of the bulb and out of the elongated slot (32) of the tube (14), (col. 3, lines 17-25).

A person of ordinary skill in the art would immediately recognize that the device shown in Figure 10 of the Abramowitz Patent is a "syringe." As defined by THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1306 (1979), of record, a "syringe" is "a device used to inject fluids into the body or draw them from it." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, at 1306, shows a picture of a syringe that employs a plunger to inject fluids through a needle, as would be immediately recognized by a person of ordinary skill in the art. The device shown in Figure 10 of Abramowitz employs a rubber "squeeze bulb" (44) in place of the plunger to inject fluids when the bulb is squeezed (See Abramowitz Patent,

col. 3, lines 17-25). A person of ordinary skill in the art would instantly recognize that the "squeeze bulb" of Figure 10 of the Abramowitz Patent is a type of syringe known as a "bulb syringe."

Of note, claim 3 of the Abramowitz Patent recites "medicament injecting means comprising a squeezable-ball containing a medicament...whereby upon squeezing the ball the medicament is ejected...." A person of ordinary skill in the art would instantly realize that the Abramowitz Patent is describing the ball (44) as an "injecting means," which is exactly what a syringe is.

In view of the above, it is clear that the Abramowitz Patent does not teach, or suggest, (i) "providing a mouth and tongue stud including means for dispensing a substance..." as recited in independent claims 21, 31, 36-39, 44 and 45 of the present application because the Abramowitz Patent discloses various devices, including a syringe, that is mounted into an earlobe. Furthermore, the Abramowitz Patent does not teach, or suggest, (ii) "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva so that the dissolved substance flows from the means for dispensing into the wearer's mouth" as recited by claims 21 and 31. On the contrary, the Abramowitz Patent discloses that an "injection means" (i.e., a bulb syringe) is required to eject a substance (i.e., medicament or perfume) from Abramowitz's device.

Another deficiency of the Abramowitz disclosure is that the tube (14) is hollow as shown in Figures 4 and 10. Therefore, the Abramowitz Patent cannot teach, or suggest, (iii)

> "the bar is a straight solid bar made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member"

as recited by independent claims 36 and 37. In fact, the device disclosed by the Abramowitz Patent employs a hollow tube (14) and would be inoperable if it employed a "solid bar" as recited by claims 36 and 37. While the Examiner appears to contend that Abramowitz's hollow tube (14) is a "solid bar," this is an unreasonable interpretation of the claim language.

While the Examiner is encouraged to give the broadest reasonable interpretation to claim terms consistent with an Applicant's disclosure, In re Hyatt, 54 U.S.P.Q.2d 1664, 1667 (Fed. Cir. 2000), the Examiner is not free to give an unreasonable interpretation to the terms in the claims. In

this case, the Examiner's interpretation of Abramowitz's hollow tube (14) as a "solid bar" in not consistent with the specification of the above-captioned application, which explicitly describes a "solid bar" (610) on page 5, lines 23-25, and illustrates it in Figure 4 of Applicant's disclosure as originally filed. On the other hand, Figure 3 of Applicants' disclosure illustrates a "central bar (100) [having] a hollow core," which is not described as a "solid bar" (See Applicant's specification, at 5, lines 15-18). In view of these facts, it is inconsistent with Applicants' specification, and unreasonable, to construe Abramowitz's hollow tube (14) to be a "solid bar," which it clearly is not.

With respect to claims 44 and 45, the Abramowitz Patent does not teach, or suggest, (iv)

> "the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed by dissolving the substance from the stud into the wearer's mouth over time in the wearer's saliva.

More specifically, the medicament or perfume injected from Abramowitz's squeeze bulb must be able to flow when squeezed, or else it cannot reasonably be ejected from such a small syringe as the one disclosed by Abramowitz. A person of ordinary skill in the art would instantly realize that the device disclosed by Abramowitz cannot dispense a substance that is in a "solid form" or in a "tablet form."

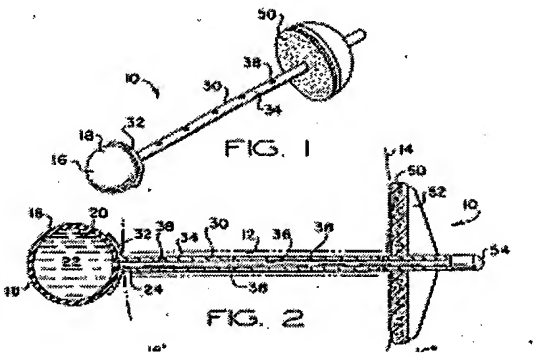
The Device Disclosed by Abramowitz is for External Use Only

The Abramowitz Patent describes an "an earlobe piecing and treating apparatus" that is placed in the piercing of an earlobe (22), (col. 2, lines 38-40, and Figure 10). The Abramowitz Patent does not teach, or suggest, that this device is suitable for use in the oral cavity of a wearer.

iv. The Edwards Patent

The Edwards Patent discloses an "apparatus for applying earlobe medicine" which is inserted into the earlobe (See Abstract). This ear apparatus is not a mouth and tongue stud and there is no teaching, or suggestion, that the apparatus would be used in the oral cavity. One skilled in the art would recognize that the apparatus (10) as shown in Figures 1 and 2 does not have the features of a

mouth and tongue stud and is not suitable for use in the mouth. For convenience, Figures 1 and 2 of the Edwards Patent are reproduced below because they illustrate the many deficiencies of the apparatus (10) disclosed by Edwards.



In particular, apparatus (10) has a relatively pointed protruding "end" (54). Mouth and tongue studs do not have points such as "end" (54) because such a pointed structure would seriously damage the mucosal surfaces in the mouth. Apparatus (10) disclosed by the Edwards Patent also has a felt pad (50) as a backing for retainer (52). Mouth and tongue studs, unlike earrings and devices for inserting into the earlobe, are restricted to certain non-toxic suitable materials for putting into the mouth. Felt is not a suitable material for the mouth. In the wet environment of the mouth, the felt would quickly degrade, break apart, and present an aspiration hazard. Furthermore, retainer (52) as shown in Figure 2 is only held in place by friction. Mouth and tongue studs cannot use simple friction retainers because the connection between the retainer and the rest of the apparatus is not robust. The mouth is a very active place with eating, drinking, speaking, and facial expressions going on. As a result, mouth and tongue studs must be securely inserted into the tongue or lip. As is commonly known by those skilled in the art, if a mouth and tongue stud falls out of its piercing and into the mouth there is a serious potential for harm from aspirating the stud or its component parts into the lungs or from choking. Generally, a threaded connection, or a weld and the like, is used to attach an "end member" of the mouth and tongue stud to the bar because this is a suitably secure connection. Friction retainers or clasps are not used.

Apparatus (10) disclosed by Edwards also has a resilient housing (16) made of neoprene, polypropylene or polyethylene so that housing (16) is squeezable (col. 2, lines 15-25, and col. 3, lines

3-10). Such a squeezable housing is unsuitable for use as a structure of a mouth and tongue stud for several reasons. First, housing (16), being compressible, would defeat one of the purposes of a mouth and tongue stud, being to enhance sexual activity. Second, the housing (16) could not hold the "antibiotic gel, petroleum or aloe-based ointments" (col. 2, lines 22-24) effectively because, once the apparatus (10) was inside the mouth, the housing would be compressed by some portion of the mouth. Thus, once in the mouth, housing (16) would not be an effective reservoir.

Furthermore, a person of ordinary skill in the art would immediately realize that the apparatus (10) disclosed by the Edwards Patent is a syringe. Specifically, apparatus (10) includes a tubular conduit (30), i.e., a needle, and a squeezable resilient housing or reservoir (16), wherein the apparatus (10) is operated to force pressurized medicament (22) through the conduit (30) and into an ear piercing when the reservoir (16) is squeezed (col. 3, lines 3-10). More specifically, a person of ordinary skill in the art would immediately realize that apparatus (10) is a "bulb" syringe wherein the reservoir (16) is the bulb. Thus, a person of ordinary skill in the art would instantly realize that the Edwards Patent does not teach, or even suggest, (i) "providing a mouth and tongue stud...," and (ii) "the substance...is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, 37, 44 and 45. Instead, the Edwards discloses a syringe mounted to an earlobe.

Given the fact that the apparatus (10) disclosed by Edwards has a different structure from the present invention, is not a mouth and tongue stud, cannot function as a mouth and tongue stud, and has no parts that would be suitable for use by a mouth and tongue stud, any rejection under 35 U.S.C. §§ 102(b) and 103(a) relying upon the Edwards reference would be untenable. For all of the above reasons, a person of ordinary skill in the art would realize that the apparatus (10) is a syringe that is inserted into an earlobe piercing (i.e., a skin piercing), and that it would be contrary to the common sense of a person of ordinary skill in the art to employ the apparatus (10) in the mouth of a wearer.

As conceded by the Examiner (Office Action, dated August 3, 2007, at 4, lines 14-16), the Edwards Patent does not teach, or suggest, "the substance comprises a breath freshener" as recited by

claim 22 and "the substance comprises a flavoring agent" as recited by claim 23.

The Edwards Patent also does not teach, or suggest, a bar that is "a straight solid bar made of metal" as recited by independent claims 36 and 37. Specifically, the Edwards Patent discloses a tubular conduit (30) that is clearly hollow as shown in Figure 3. Therefore, the Edwards Patent cannot teach, or suggest, (iii)

> "the bar is a straight solid bar made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member"

as recited by independent claims 36 and 37. In fact, the device disclosed by the Edwards Patent employs a hollow tube (30) and would be inoperable if it employed a "solid bar" as recited by claims 36 and 37. While the Examiner appears to contend that Edward's hollow tube (30) is a "solid bar," this is an unreasonable interpretation of the claim language.

While the Examiner is encouraged to give the broadest reasonable interpretation to claim terms consistent with an Applicant's disclosure, In re Hyatt, 54 U.S.P.Q.2d 1664, 1667 (Fed. Cir. 2000), the Examiner is not free to give an unreasonable interpretation to the terms in the claims. In this case, the Examiner's interpretation of Edward's hollow tubular conduit (30) as a "solid bar" in not consistent with the specification of the above-captioned application, which explicitly describes a "solid bar" (610) on page 5, lines 23-25, and illustrates it in Figure 4 of Applicant's disclosure as originally filed. On the other hand, Figure 3 of Applicants' disclosure illustrates a "central bar (100) [having] a hollow core," which is not described as a "solid bar" (See Applicant's specification, at 5, lines 15-18). In view of these facts, it is inconsistent with Applicants' specification, and unreasonable, to construe Edward's hollow tubular conduit (30) to be a "solid bar," which it clearly is not.

The Edwards Patent also does not teach, or suggest, (iv)

> "the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed by dissolving the substance from the stud into the wearer's mouth over time in the wearer's saliva"

as recited by claims 44 and 45. More specifically, the medicaments, such as are in a gel form or in an

ointment form, injected from Edward's squeezable reservoir (16) must be able to flow when squeezed (col. 2, lines 19-24, and col. 3, lines 5-9), or else it cannot reasonably be ejected from such a small syringe as the one disclosed by Edwards. A person of ordinary skill in the art would instantly realize that the device disclosed by Edwards cannot dispense a substance that is in a "solid form" or in a "tablet form."

The Device Disclosed by Edwards is for External Use Only

The Edwards Patent describes an "an apparatus for applying earlobe medication" that is placed in the piercing of an earlobe, (col. 1, lines 38-40). The Edwards Patent does not teach, or suggest, that this device is suitable for use in the oral cavity of a wearer.

v. The Lefkowitz Patent

The Lefkowitz Patent discloses a "gingival breath deodorizer and bite guard" as shown in Figure 1, which is reproduced below for convenience. The body (10) of the device includes a bladder vesicle (24) of a "flexible duckbill construction" with a filing aperture (28) at one end and a dispensing valve (26) at the other end (col. 4, lines 37-51). When bladder (24) is pressed, a "breath deodorizing liquid" is discharged from the valve (26), (col. 4, lines 46-51).

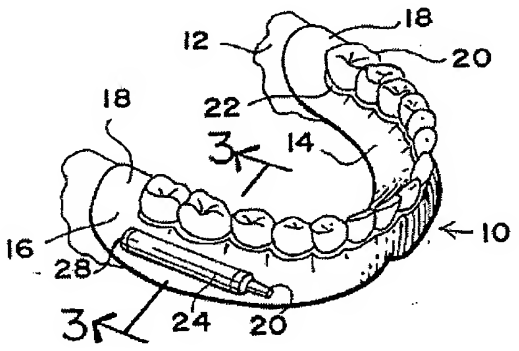


Figure 1 of Lefkowitz Patent

A person of ordinary skill in the art would immediately realize that the "gingival breath deodorizer and bite guard" device disclosed by the Lefkowitz Patent is just another syringe. The

Lefkowitz Patent does not teach, or suggest, , (i) "providing a mouth and tongue stud...," and (ii) "the substance...is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, 37, 44 and 45, (iii) "a straight solid bar made of metal" as recited by independent claims 36 and 37, and (iv)

> "the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed by dissolving the substance from the stud into the wearer's mouth over time in the wearer's saliva"

as recited by claims 44 and 45.

vi. Summary of the Disclosures

The Kapling Patent discloses a conventional bar bell stud that is inserted through a passageway in a user's tongue. The Kapling Patent does not teach, or suggest, any "means for dispensing a substance" and/or any related features.

The Abramowitz Patent discloses an earhole piercing and treating apparatus that is inserted into the piercing of an earlobe. The device disclosed by Abramowitz is a syringe and it is not suitable for use in a wearer's mouth.

The Edwards Patent discloses an apparatus for applying earlobe medicine that is inserted into the piercing of an earlobe. The device disclosed by Edwards is another syringe and it is also not suitable for use in a wearer's mouth.

The Lefkowitz Patent discloses a gingival breath deodorizer and bite guard that is used in a wearer's mouth. The device disclosed by the Lefkowitz Patent includes yet another syringe.

The combination of the disclosures of the Kapling Patent, the Abramowitz Patent, the Edwards Patent, and the Lefkowitz Patent does not teach, or even suggest, (i) "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" and (ii) "the substance...is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, 37, 44 and 45, (iii)

> "the bar is a straight solid bar made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for

dispensing a substance is formed in one or both of the first end member and the second end member"

as recited by independent claims 36 and 37, and (iv)

"the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed by dissolving the substance from the stud into the wearer's mouth over time in the wearer's saliva"

as recited by claims 44 and 45.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against any claim of the above-captioned application.

vii. Dispensing a Substance Using Saliva is Not Taught by Kapling, Abramowitz, Edwards or Lefkowitz

As admitted by the Examiner (Office Action, dated March 24, 2008, at 6, lines 5-7, and at 11, lines 8-9), the combination of the Kapling Patent, the Abramowitz Patent, the Edwards Patent, and the Lefkowitz Patent fails to teach, or suggest, "the substance...is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36, 37, 44 and 45. Instead, (a) the Examiner **speculates** that some of the substance remaining in the syringe needles (i.e., Abramowitz's slotted tube (14) or Edwards' tubular conduit (30)) would subsequently be dissolved by the wearer's saliva and therefore be dispensed over time in accordance with the presently claimed invention, or in the alternative, (b) the Examiner contends that after the substance is injected from the syringe it is "dispensed...into the wearer's mouth" as it dissolves in the saliva of the wearer (Office Action, dated March 24, 2008, at 6, lines 7-17; and at 11, lines 9-19). The Examiner's theories are untenable and fail to support a prima facie case of obviousness for the following reasons.

A prima facie case of obviousness must be based on substantial evidence and not on what the Examiner contends is "common sense." In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). In this case, the Examiner contends that "obviously" saliva will travel from a wearer's mouth and into the needles disclosed by the Abramowitz Patent and the Edwards Patent, and then the saliva will

dissolve some of the substance in the needles and then flow back out again (See Office Action, dated March 24, 2008, at 6, lines 7-17; and at 11, lines 9-19). The Examiner's contention is flawed because (1) saliva is a viscous substance and there is no evidence of record that would teach, or suggest, that the slotted tube (14) of Abramowitz, and/or the tubular conduit (30) of Edwards, are dimensioned so that saliva, or any other bodily fluid, should spontaneously flow up into these needles. Even assuming that such a saliva backflow would occur (which is a wholly invalid assumption), both the Abramowitz Patent and the Edwards Patent disclose using a squeezable bulb to eject medicament. As would be instantly understood by a person of ordinary skill in the art, once the bulb (44) of Abramowitz, or bulb (16) of Edwards, has been squeezed to eject medicament there will be a negative pressure in the bulb. This negative pressure, if sufficient to draw saliva into the tubes (14) or (30) in the first place would subsequently prevent saliva from exiting the tubes (14), (30) once saliva has been sucked in.

In other words, even if viscous saliva was sucked up into the tubes (14) or (30), as the Examiner contends, it would be trapped in the tubes (14), (30) by the negative pressure generated by the bulb (44) or (16), respectively, and by the fact that saliva is viscous and sticky. Consequently, even if saliva were drawn into the tubes (14) or (30), it would form a saliva plug trapping the substance within the tubes (14) or (30) instead of "dispensing" the substance dissolved in saliva by flowing back out of the tubes (14) or (30) as the Examiner contends.

The Examiner's second theory, wherein the substance once dispensed from the device by the syringe mechanism would be further "dispensed...into the wearer's mouth" by dissolving the substance in saliva while the substance is in the wearer's mouth, is untenable because it is based on an unreasonable interpretation of the claim language. Specifically, while the Examiner is encouraged to give Applicant's claims the broadest reasonable interpretation consistent with the specification, In re Hyatt, 54 U.S.P.Q.2d 1664, 1667 (Fed. Cir. 2000), **the Examiner is not free to give an unreasonable interpretation to the claimed invention**. In this case, the Examiner has not given a reasonable interpretation to the invention as claimed. Specifically, independent claims 21, 31, 36, 37,

44 and 45 recite "the substance is dispensed...by dissolving the substance over time in the wearer's saliva." There are many definitions of the word "dispense" and the Examiner is encouraged to give a broad interpretation of this term. Because Applicant's specification does not explicitly define the term "dispense," it should be given its ordinary meaning as would be understood by a person of ordinary skill in the art. Phillips v. AWH Corporation, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005)(*en banc*). Furthermore, encyclopedias and dictionaries may be consulted to establish what the ordinary meaning of a claim term may be. Phillips v. AWH Corporation, 415 F.3d at 1318. THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 379 (1979), of record, gives a definition for the word "dispense," which is "[t]o deal out or distribute in parts or portions." Thus, a broad reasonable interpretation of the claimed phrase "is dispensed...by dissolving the substance over time in the wearer's saliva" is that the substance is "dealt out or distributed in parts or portions by dissolving the substance over time in the wearer's saliva." This broad interpretation is consistent with Applicant's original specification, at 5, lines 1-6.

However, there is more to the language of the independent claims. The full phrase, recited by claims 21, 31, 36, 37, 44 and 45, is "the substance is dispensed **into** the wearer's mouth by dissolving the substance over time in the wearer's saliva." Thus, the broadest reasonable interpretation of the claims consistent with Applicant's specification is that the substance is "dealt out or distributed in parts or portions **into** the wearer's mouth by dissolving the substance over time in the wearer's saliva." Because Applicant's specification does not explicitly define the term "mouth," it should be given its broadest ordinary meaning as would be understood by a person of ordinary skill in the art, and consultation to encyclopedias and dictionaries may establish what the ordinary meaning of the term may be. Phillips v. AWH Corporation, 415 F.3d at 1316 and 1318. THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 379 (1979), of record, gives multiple definitions for the word "mouth," including

> "**a.** The body opening through which an animal takes in food; the oral cavity.
> **b.** The system of related organs including the lips, teeth, tongue, and associated parts, with which food is chewed and swallowed and sounds and speech are articulated."

In view of the above, **the broad reasonable interpretation of the claimed phrase "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" is that the substance is "dealt out or distributed in parts or portions into the wearer's mouth, which includes any of the tongue, lips, oral cavity, and associated parts, by dissolving the substance over time in the wearer's saliva**." This broad interpretation is consistent with Applicant's original specification, at 5, lines 1-6. A person of ordinary skill in the art would instantly appreciate that the claimed invention passively dispenses the substance **into** the mouth by dissolving it using the wearer's saliva. A person of ordinary skill in the art would also instantly appreciate that Abramowitz and Edwards disclose actively dispensing a substance by injection. A person of ordinary skill in the art, realizing that the claimed invention pertains to passive dispensing of the substance into the mouth using saliva, would understand that it is distinguished from Abramowitz's and Edwards' active injection process.

The Examiner erroneously reads additional limitations into, and/or grossly misconstrues, the language of Applicant's claims. The Examiner admits that the devices of both the Abramowitz Patent and the Edwards Patent "dispense" by injection. Specifically, the Examiner states that

> "[the substance] will be dissolved over time in the wearer's saliva **after being injected into the piercing** since time is needed to completely dissolve the substance...."
> (Office Action, dated March 24, 2008, at 6, lines 14-16, and at 11, lines 17-19, emphasis added).

Applicant agrees with the Examiner that both Abramowitz and Edwards disclose injecting a medication into an earlobe piercing. However, Applicant contends that Abramowitz and Edwards fail to disclose injecting medication into a piercing located in the mouth of a wearer. Assuming, *arguendo*, that the combination of Kapling with either Abramowitz or Edwards teaches injecting medication into a piercing located in the mouth of a wearer (which, of course, is a wholly invalid assumption), the Examiner's argument still fails for the following reasons.

Specifically, the Examiner contends that once the medication is injected into the piercing, it will then be "dispensed as it travels out of the piercing and it will be dissolved over time in the

wearer's saliva after being injected into the piercing since time is needed to completely dissolve the substance" (Office Action, dated March 24, 2008, at 6, lines 12-17; and at 11, lines 15-19, emphasis added). In other words, the Examiner argues that after medication is injected from the hypothetical device created by the Examiner (i.e., the combination of Kapling and Abramowitz, or the combination of Kapling and Edwards) and into a pierced orifice, it then is "dispensed" from the pierced orifice into the wearer's mouth by dissolving the medication in saliva. However, **the pierced orifice is not part of Examiner's hypothetical device but is a part of the wearer's mouth**.

The Examiner's argument wherein medication leaving the pierced orifice would meet the language of the claimed invention is untenable because once the substance has been injected **into** the piercing, which the Examiner contends is in the mouth of a wearer, it has already been "dispensed" **into** the pierced orifice by injection as admitted by the Examiner (Office Action, dated March 24, 2008, at 6, line 15; and at 11, lines 15-16). Therefore, once the substance has been injected **into** the piercing it has been "**dispensed into the wearer's mouth**" as that term is used in the present claims. Any subsequent travel of the substance once it is already in the wearer's mouth cannot reasonably construed to meet the claimed limitation "dispensed into the wearer's mouth" because the substance is already in the wearer's mouth.

In sum, the Examiner concedes that the hypothetical device injects medication from the device into the piercing without using saliva. The Examiner erroneously speculates that perhaps some of saliva will travel into the needle of the syringe, dissolve some trace amount of substance remaining in the syringe needle, and then flow back out again. As discussed above, there is no evidence that the Examiner's hypothetical device would be subject to the flow of saliva into the needle and, as would be immediately understood by a person of ordinary skill in the art, such backflow of viscous, sticky saliva is unlikely given the tiny structures disclosed by Abramowitz and Edwards. Furthermore, in view of the fact that following injection the bulb syringe of the Examiner's hypothetical device would generate a negative pressure, if any saliva were drawn into the needle following injection, a person of ordinary skill in the art would expect it to be trapped in the needle.

In the alternative, the Examiner erroneously contends that once the substance has been injected from the hypothetical device into a mouth piercing (which is part of the mouth) that it has not been "dispensed into the wearer's mouth" until the substance dissolves from the piercing and moves into the oral cavity (which is another part of the mouth). In other words, the Examiner erroneously ignores the fact that once the substance has moved from the Examiner's hypothetical device to the piercing that the substance has been "dispensed into the wearer's mouth." The Examiner also erroneously ignores the fact that movement of the substance from one part of the wearer's mouth (i.e., the piercing) to another part of the wearer's mouth (i.e., the oral cavity) cannot be reasonably construed as "dispensing" of the substance "into the wearer's mouth."

For all of the above reasons, the Examiner's contention that the hypothetical device "obviously" operates so that "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" is untenable. For all of the above reasons, the Examiner's argument wherein the substance is dispensed "into the wearer's mouth" as it moves from the piercing to the oral cavity is flawed because it depends on an unreasonable interpretation of the claimed invention and on an unreasonable interpretation of the disclosures of the Kapling Patent, the Abramowitz Patent and the Edwards Patent. For all of the above reasons, the combination of the Kapling Patent, the Abramowitz Patent and the Edwards Patent does not teach, or suggest, "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by Applicant's claims.

viii. No Legitimate Reason to Justify the Combination of Patents

The Examiner has failed to establish a proper teaching, motivation, suggestion, or any legitimate reason, to combine the Kapling Patent, the Abramowitz Patent, the Edwards Patents, and the Lefkowitz Patent to arrive at the claimed invention. See KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Rouffet, 47 U.S.P.Q.2d 1453, 1456 (Fed. Cir. 1998). In particular, the common sense of those skilled in the art may demonstrate why some combinations are

obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007). In this case, the Examiner has failed to establish a proper teaching, suggestion, motivation, or other legitimate reason, to justify the combination of the Kapling Patent, the Abramowitz Patent, the Edwards Patents, and the Lefkowitz Patent because the combination falls short of the claimed invention for all of the reasons discussed above. Furthermore, the Examiner has failed to adduce any legitimate reason to justify the combination for the following reasons.

The Kapling Patent discloses a conventional bar bell stud for inserting into a tongue piercing, and the conventional bar bell stud does not include any means for dispensing a substance. The Abramowitz Patent discloses an earhole piercing and treating apparatus that is inserted into the piercing of an earlobe, and this apparatus is a syringe. The Abramowitz Patent discloses that its "injection means" structure is used to eject medicament into an ear piercing in order to treat sore, infected ear piercings (Abramowitz Patent, col. 1, lines 43-48; col. 2, lines 11-14; col. 3, lines 17-25, and Figure 10). The Edwards Patent discloses an apparatus for applying earlobe medicine that involves another syringe design. The Edwards Patent discloses using a squeezable reservoir (16) and attached tubular conduit (30) to inject medicament into the piercing of an earlobe by squeezing the reservoir (16) in order to avoid frequent infection of the earlobe piecing (Edwards Patent, col. 1, lines 28-35; and col. 3, lines 2-12).

The Examiner contends that it would have been obvious to a person of ordinary skill in the art, at the time the present invention was made, to have modified the bar bell disclosed by Kapling to include the syringe features disclosed by Abramowitz and by Edwards in order to clear up infections in the wearer's tongue or mouth (Office Action, dated March 24, 2008, at 5, lines 9, to 6, line 5). However, the Examiner's reason for the combination is not legitimate because (i) infections of mouth piercings are rare, and (ii) the treatment of mouth piercing infections does not involve the use of medicaments dispensed by a syringe into the piercing.

As disclosed by the Edwards Patent, infection of earlobe infections are frequent (Edwards Patent, col. 1, lines 28-31). This fact is further supported by Barton Schmidt, *Your Child's Health:*

The Parent's Guide to Symptoms, Emergencies, Common Illnesses, Behavior and School Problems, 524-527 (Bantam Books 1991), of record. On the other hand, mouth infections following trauma are rare (See, e.g., Barton Schmidt, *Your Child's Health: The Parent's Guide to Symptoms, Emergencies, Common Illnesses, Behavior and School Problems*, 77-78 (Bantam Books 1991), of record). A person of ordinary skill in the art would know that pierced earlobes have a relatively high rate of infection, whereas mouth piercings do not, and that this difference in infection rates is due to the fact that the earlobe is a poorly vasculaturized structure that is colonized with aerobic gram positive bacteria, whereas mouth structures are highly vasculaturized and are colonized mainly with anaerobic bacteria. A person of ordinary skill in the art would also know that ear piercings may be treated by applying rubbing alcohol to the post of an earring (See, e.g., Barton Schmidt, *Your Child's Health: The Parent's Guide to Symptoms, Emergencies, Common Illnesses, Behavior and School Problems*, 526 (Bantam Books 1991), of record). On the other hand, a person of ordinary skill in the art would know that treatment of mouth trauma involves use of anti-septic mouthwash (See, e.g., M. Chen et al., *Tongue Piercing: a New Fad in Body Art*, 172 BR. DENT. J. 87 (1992), of record), which a person of ordinary skill in the art would also know is used in amounts of about 30 cc to 60 cc as a rinse. A person of ordinary skill in the art would also know that a truly infected tongue piercing is likely to be complicated by tongue swelling and airway compromise so that treatment would require removal of any tongue jewelry (See, e.g., C.S. Perkins et al., *A Complication of Tongue Piercing*, 182 BR. DENT. J. 147-148 (1997), of record).

In sum, a person of ordinary skill in the art would know that while infected earlobe piercings are common and are generally caused by gram positive aerobic bacteria, infected piercings of the mouth are rare and are generally caused by normal oral flora (i.e., anaerobic bacteria). Furthermore, a person of ordinary skill in the art would know that while infected earlobe piercings may be treated with topical anti-septics and antibiotics while maintaining the earring post in the piercing, infected mouth piercings would be treated with voluminous mouthwashes and removal of any jewelry. In view of these facts, a person of ordinary skill in the art would have no legitimate reason to modify the

device disclosed by the Kapling Patent to incorporate features disclosed by either the Abramowitz Patent or the Edwards Patent because earlobe piercings are caused by different kinds of bacteria from mouth piercings and are treated differently. In particular, the Examiner has established no legitimate reason to combine either Abramowitz and/or Edwards with Kapling because (i) conventional medical wisdom would counsel against retaining mouth jewelry in an infected mouth piercing, and (ii) there is no evidence that the small amount of any anti-septic substance that the structures disclosed by Abramowitz and/or Edwards could dispense would be clinically effective in treating and/or preventing any infection of a piercing of the mouth.

In other words, different parts of the body are prone to substantially different types of infections that are also managed differently using substantially different medical therapies. The articles discussed above demonstrate these facts. The Examiner has adduced no facts whatsoever to show that medical therapies for treating earlobe piercing infections are suitable for treating infections of a mouth piercing. On the other hand, Applicant has demonstrated by the articles discussed above that medical therapies for treating an earlobe piercing infection are not suitable for treating an infection of a mouth piercing. The Examiner has adduced no facts to rebut these medical facts demonstrated by Applicant.

The Lefkowitz Patent also fails to provide a legitimate reason to justify the combination of Kapling with either Abramowitz and/or Edwards because the device disclosed by Lefkowitz dispenses a breath deodorizing solution that may contain a medication for deodorizing breath (Lefkowitz Patent, col. 2, lines 64-68). The Lefkowitz Patent does not teach, or suggest, a device for dispensing medication for treating an infected piercing of the mouth, and the Lefkowitz Patent does not teach, or suggest, that a bar bell stud could be used to dispense a breath deodorizer or related breath deodorizing medication.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against the invention recited by independent claims 21, 31, 26, 37, 44 and 45.

ix. No Reasonable Expectation of Success Even if the Combinations Proposed by the Examiner Were Made

A proper rejection under Section 103 requires showing (1) that a person of ordinary skill in the art would have had a legitimate reason to attempt to make the composition or device, or to carry out the claimed process, and (2) that the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). In this case, assuming that the Examiner has established a legitimate reason to justify the combination of the Kapling Patent with the Abramowitz Patent and/or the Edwards Patent (which is an invalid assumption), the Examiner has still failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of success of arriving at the claimed invention if the combination were made.

Claims 36 and 37 recite "the bar is a straight solid bar made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member." If a hypothetical device were made according to the Examiner by combining the features disclosed by Abramowitz or Edwards with the bar bell stud of Kapling, the result would be inoperative if the tube (14) or (30) were made "solid" (i.e., not hollow). As shown by Figure 10 of Abramowitz, and by Figure 2 of Edwards, it is necessary for the tube to be hollow in order for medicament to be ejected from the reservoirs (44) and (16), respectively. Otherwise, the hypothetical device proposed by the Examiner would be inoperative because, if the tube is made solid and not hollow, then the medicament remains trapped in the reservoir.

The Federal Circuit has ruled that a combination of prior art that would be inoperative actually teaches away from the combination and cannot establish a prima facie case of obviousness. McGinley v. Franklin Sports Inc., 60 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 2001). Therefore, the Examiner has failed to establish a prima facie case of obviousness against claims 36 and 37 because any combination of Kapling with either Abramowitz and/or Edwards with the tube made "solid"

instead of hollow would be inoperative.

Claims 44 and 45 recite "wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed by dissolving the substance from the stud into the wearer's mouth over time in the wearer's saliva." The device resulting from the combination of Kapling with either Abramowitz and/or Edwards would have a squeezable reservoir (44), (16) in which medicament is expressed upon squeezing. However, if the medicament is in a "solid form" or a "tablet form," it would not be ejected from the syringe upon squeezing of the reservoir (44), (16) as would be instantly realized by a person of ordinary skill in the art. Consequently, the Examiner has failed to establish a reasonable expectation of success that, upon combining Kapling with Abramowitz and/or Edwards, the resulting hypothetical device could dispense medication that is stored in the reservoir in a solid form or in a tablet form as claimed. In fact, if the medicament were in a solid form or in a tablet form, then the device proposed by the Examiner would be inoperative. Therefore, the Examiner has failed to establish a prima facie case of obviousness against claims 44 and 45 because the Examiner has failed to demonstrate that the combination of Kapling with either Abramowitz and/or Edwards would result in a device that dispenses medicament that is stored in the reservoir in a solid form or in a tablet form.

With respect to claims 21, 31, 36, 37, 44 and 45, the Examiner has failed to show a reasonable expectation of success that the combination of Kapling with Abramowitz and/or Edwards would operate to dispense the substance "into the wearer's mouth by dissolving the substance over time in the wearer's saliva." On the contrary, the Examiner explicitly admits that the proposed combination does not teach operation in such a manner (Office Action, dated March 24, 2008, at 6, lines 5-7, and at 11, lines 8-9). Instead, the Examiner speculates that perhaps the device could operate in such a manner. Applicant contends that such speculation as to the operation of the hypothetical construct resulting from the Examiner's combination of Kapling, Abramowitz, Edwards, and Lefkowitz falls short of a "reasonable expectation of success." Furthermore, Applicant has demonstrated, as discussed above, that the Examiner's hypothetical construct is not likely to operate

in the manner claimed by independent claims 21, 31, 36, 37, 44 and 45. Therefore, the Examiner has failed to establish a prima facie case of obviousness against claims 21, 31, 36, 37, 44 and 45 because the Examiner has failed to demonstrate that the combination of Kapling with either Abramowitz and/or Edwards would result in a device that dispenses medicament into the mouth of a wearer by dissolving the substance in the wearer's saliva.

In addition to failing to demonstrate a reasonable expectation of success, the Examiner has failed, for all of the above reasons, to demonstrate that the combination of Kapling, Abramowitz, Edwards, and Lefkowitz is enabling. The Federal Circuit has held that the combination of the prior art must be enabled. In re Kumar, 418 F.3d 1361, 1369 (Fed. Cir. 2005). Therefore, the Examiner has additionally failed to establish a prima facie case of obviousness because the Examiner has failed to establish that the combination of Kapling, Abramowitz, Edwards and Lefkowitz is enabled.

III. CONCLUSION

Claims 38 and 39 are in condition for allowance for the reasons of record.

In view of the present amendment, claims 21-27, 31, 36-39 and 42-49 are in compliance with 35 U.S.C. §112.

With respect to claims 21-27, 31, 36, 37 and 42-49, the Examiner has failed to establish a prima facie case of obviousness against these claims because the combination of the Kapling Patent, the Abramowitz Patent, the Lefkowitz Patent, and the Edwards Patent, (i) fails to teach each and every limitation of the claims, (ii) the Examiner has failed to establish any legitimate reason to justify the combination, and (iii) the Examiner has failed to establish that the combination would be enabling and/or that by making the combination a person of ordinary skill in the art would have a reasonable expectation of arriving at the claimed invention.

For all of the above reasons, claims 21-27, 31, 36-39 and 42-49 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed Applicant.

Respectfully submitted,

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